

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 19-662 (CFC)
)	
NATERA, INC.,)	
)	
Defendant.)	

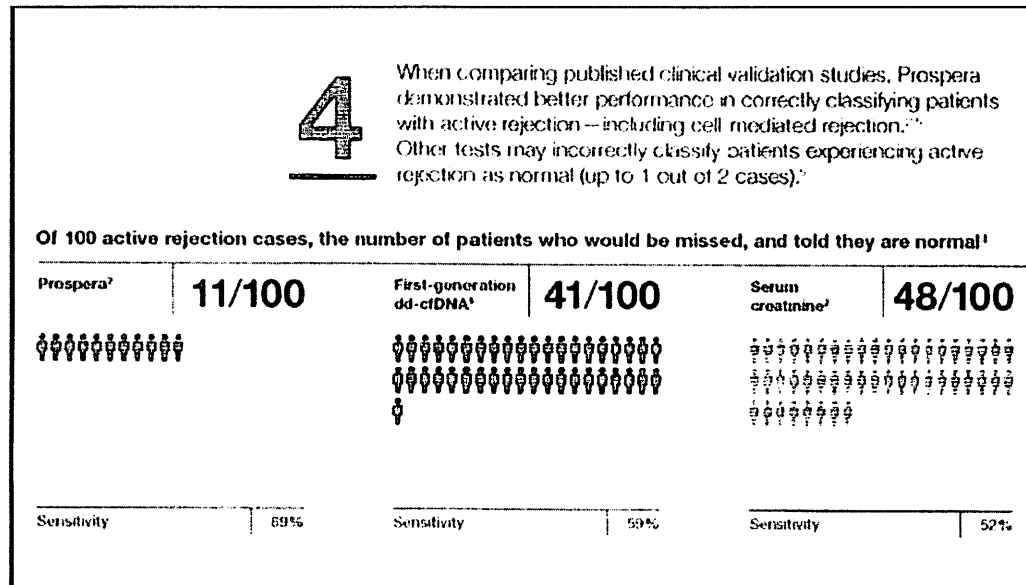
PROPOSED STIPULATED ORDER

Before the Court are CareDx, Inc.'s ("CareDx") and Natera, Inc.'s ("Natera") respective Motions for injunctive relief. (D.I. 349-352.) The Court, having considered the briefing, evidence, and arguments of the parties, is of the opinion that injunctive relief is warranted in this case.

Accordingly, it is hereby **ORDERED** that:

A. The Court hereby permanently enjoins Natera, Inc. ("Natera"), and any of its officers, directors, agents, servants, employees, attorneys, successors, and assigns who receive actual notice hereof, and those persons acting in concert or participation with any of them who receive actual notice hereof, from conveying, explicitly or implicitly, in promotional, training, and/or educational materials the following claims (the "Natera False Advertising Claims") based on the scientific paper or combination of scientific papers that were cited in and by those claims to support them:

1. “More sensitive and specific than current assessment tools across all types of rejection.”
2. “Unparalleled precision”
3. The advertisement below:



4. The statements below:

Natera Announces Publication of Kidney Transplant Validation Study, Demonstrating Superior Data in Detection of Clinical and Subclinical Rejection

Represents Successful Achievement of All 2018 Commercialization Milestones, on Path to 2019 Launch

SAN CARLOS, Calif., Jan. 7, 2019 /PRNewswire/ -- Natera, Inc. (NASDAQ: NTRA), a leader in cell-free DNA, today announced clinical validation study results published in the *Journal of Clinical Medicine*,¹ demonstrating the highly accurate performance of its donor-derived cell-free DNA (dd-cfDNA) test for active allograft rejection in kidney transplant recipients, including higher sensitivity and nearly 18% higher area under the curve (AUC) than the competitive dd-cfDNA assay.^{1,2} The study also reports the first accurate detection of T-cell mediated rejection (TCMR) and subclinical rejection. This marks the successful completion of all 2018 commercialization milestones, and is in line with the company's plan to secure Medicare coverage and commercially launch its test in 2019.

5. The statements below:

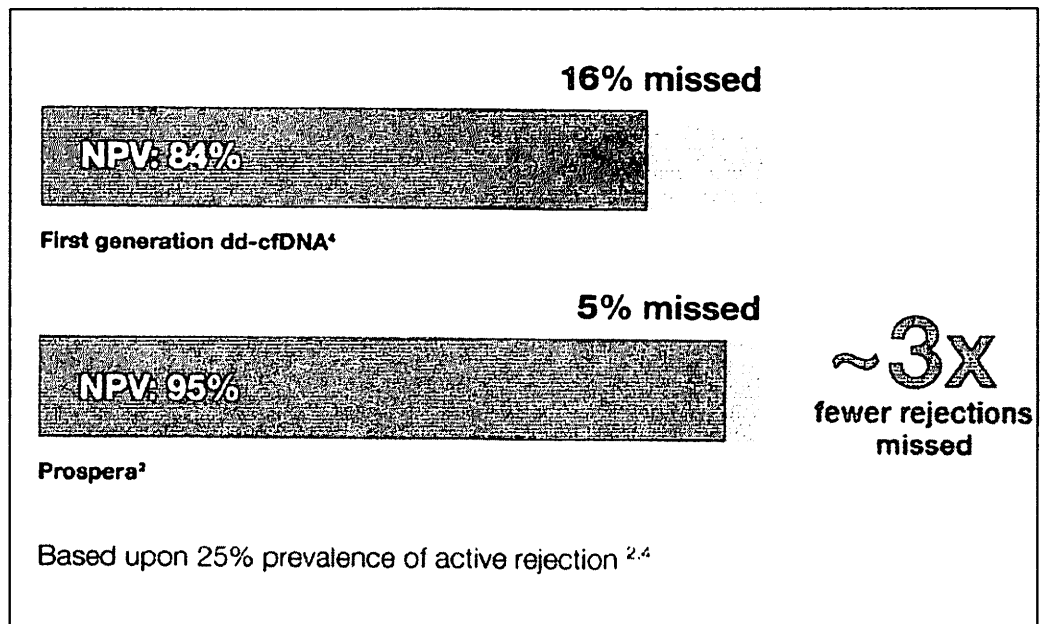
Natera Announces Publication of Analytical Validation Study
Demonstrating Superior Precision of Its Kidney Transplant
Rejection Assay

Core Technology Delivers Superior Analytical
Performance, Underpins Outstanding Clinical
Performance

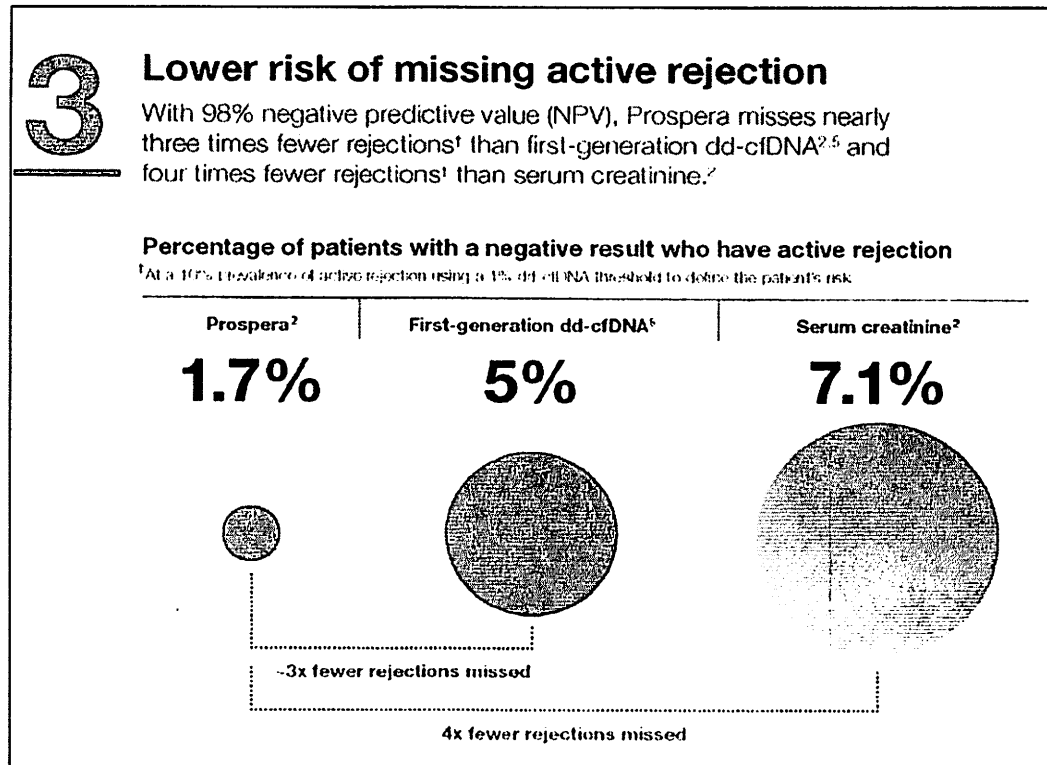
SAN CARLOS, Calif., Feb. 22, 2019 /PRNewswire/ -- Natera, Inc. results to be published online

performance in detecting active allograft rejection (AR). In its recently published clinical
validation study,⁴ Natera reported higher sensitivity (89% vs. 59%) and higher area under the
curve (0.87 vs. 0.74) than the competing dd-cfDNA assay.^{4,5} In that study, Natera also

6. The advertisement below:





7. The advertisement below:



8. The advertisement below:


Stronger test performance demonstrated with unique clinical capabilities

	 natera	 CareDx
• Largest dd- cfDNA validation study (217 patients)	217	107
• Higher area under the curve; driven by superior clinical data	0.87	0.74
• First test to accurately detect TCMR (about 1/3 of all AR cases)	10/10	3/11
• First test to consistently detect subclinical rejection	92%	N/A
• 5x higher repeatability at 0.6% donor fraction (CV)	1.85	9.2

¹¹


9. The advertisement below:

Highly sensitive across a range of rejection types and patients



Broad distribution of rejection types


- Subclinical rejection
- T-cell mediated rejection IA/IB/IIIB
- Antibody-mediated rejection
- C4d-positive antibody-mediated rejection
- Acute rejection



Variety of ethnic & racial demographics

- Hispanic / Latino (n=50)
- Caucasian (n=74)
- African American (n=31)
- Asian (n=31)
- Ages:
 - Below 18 years of age (n=49)
 - 18 – 40 years of age (n=68)
 - Above 40 (n=100)

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B. For any of the Natera False Advertising Claims appearing in a medium under Natera's control, Natera shall take all actions necessary to permanently remove from public view those Natera False Advertising Claims.

C. For any Natera False Advertising Claims published by others, Natera shall take reasonable actions to request their removal from public view as early as practicable.

D. CareDx and any of its officers, directors, agents, servants, employees, attorneys, successors, and assigns who receive actual notice hereof, and those persons acting in concert or participation with any of them who receive actual notice hereof, are permanently enjoined from representing, explicitly or implicitly, in commercial advertising or promotion the following claims (the "CareDx False Advertising Claims"):

1. CareDx had no involvement with the Melancon study.¹

2. CareDx did not provide funding for the Melancon study.

E. For any of the CareDx False Advertising Claims appearing in a medium under CareDx's control, CareDx shall take all actions necessary to permanently remove such claims from public view.

F. For any of the CareDx False Advertising Claims published by others, CareDx shall take reasonable actions to request their removal from public view as early as practicable

Dated: August 4, 2023

Respectfully submitted,

FARNAN LLP

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Brian E. Farnan

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Attorneys For Defendant Natera, Inc.

IT IS SO ORDERED.

Date: 8.7.23



The Honorable Colm F. Connolly
Chief United States District Judge

¹ Joseph K Melancon *et al.*, *Donor-Derived Cell Free DNA: Is It All the Same?*, 1 KIDNEY360 1118 (2020) (DOI: 10.34067/KID.0003512020).